

**REMARKS**

Applicants acknowledge receipt of the Office Action mailed October 1, 2008.

In the Office Action, the Examiner objected to the Information Disclosure Statement filed on October 12, 2006; objected to the specification; rejected claim 17 under 35 U.S.C. § 112, second paragraph; rejected claims 1 and 9 under 35 U.S.C. § 102(b) as being anticipated by *Rhett* (U.S. Patent No. 5,839,091); and rejected claims 2-8 and 10-34 under 35 U.S.C. § 103(a) as being unpatentable over *Rhett* in view of *Ganz* (WO 02/064812).

By this Amendment, Applicants amend the specification and claims 1, 6-8, 10, 17, 21, 25, and 30, cancel claims 20, 24, and 31, without prejudice or disclaimer, and add new claims 35 and 36. Claims 1-19, 21-23, 25-30, and 32-36 are pending. Of these claims, claims 1, 6-10, 17, 21, 25, 30, 35, and 36 are independent.

Applicants traverse the objections and rejections above and respectfully request reconsideration for at least the reasons that follow.

**I. INFORMATION DISCLOSURE STATEMENT**

The Information Disclosure Statement (IDS) submitted on October 12, 2006 stands objected to under 37 C.F.R. § 1.98(a)(3) because it allegedly "does not include a concise explanation of the relevance . . . of each patent listed that is not in the English language, specifically FR 2239167, DE 69417908, and ES 2160486." (*Office Action*, p. 2, para. 4). Applicants re-submit herewith copies of FR 2239167, DE 69417908, and ES 2160486, with corresponding English-language abstracts. Applicants respectfully request that the Examiner consider these documents and indicate that they were

considered by making appropriate notations on the attached supplemental IDS Form PTO/SB/08.

**II. 35 U.S.C. § 112, SECOND PARAGRAPH, REJECTION**

Claim 17 stands rejected under 35 U.S.C. § 112, second paragraph. Specifically, the Examiner asserts that, “[c]laim 17 recites the limitation ‘said tissue sample’ in lines 4-5. There is insufficient antecedent basis for this limitation in the claim.” (*Office Action*, p. 3, para. 6). Applicants submit that the rejection of claim 17 has been rendered moot by the amendments to claim 17. Applicants therefore request that the rejection of claim 17 under 35 U.S.C. § 112, second paragraph, be withdrawn.

**III. 35 U.S.C. § 102(b) REJECTION**

Applicants traverse the rejection of claims 1 and 9 under 35 U.S.C. § 102(b) as being anticipated by *Rhett*. Applicants respectfully submit that independent claims 1 and 9 distinguish over *Rhett* at least for the reasons described below.

In order to properly establish that *Rhett* anticipates Applicants’ claimed invention under 35 U.S.C. § 102, each and every element of each of the claims in issue must be found, either expressly described or under principles of inherency, in that single reference. Furthermore, “[t]he identical invention must be shown in as complete detail as is contained in the ... claim.” See M.P.E.P. § 2131, quoting *Richardson v. Suzuki Motor Co.*, 868 F.2d 1126, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

Amended independent claim 1 recites an automatic staining apparatus, comprising: “at least one removable reagent container positioned within a reagent section; at least one slide; . . . a control element to which said robotic element is responsive; and an image-capture 2-D optical sensor configured to two dimensionally

image at least one element in said automatic staining apparatus, wherein the control element monitors insertion or removal of the at least one removable reagent container and the at least one slide during processing protocol steps."

Independent claim 9 recites an automatic staining apparatus, comprising: "at least one reagent container in a reagent section; at least one first sample contained on a slide in a first slide section; [and] at least one second sample contained on a slide in a second slide section, wherein said first slide section and said second slide section are separated by said reagent section."

*Rhett* appears to disclose a method and apparatus for automatic tissue staining. The automatic staining apparatus includes an electromechanical automatic staining device that is coupled to a personal computer system using an interface card. An autostainer control program runs on the personal computer system. The autostainer control program allows a user to simply program the automatic staining apparatus using simple commands entered in a graphical user interface. (*Rhett*, Abstract).

*Rhett*, however, does not disclose "at least one removable reagent container positioned within a reagent section; at least one slide; . . . a control element to which said robotic element is responsive; and an image-capture 2-D optical sensor configured to two dimensionally image at least one element in said automatic staining apparatus, wherein the control element monitors insertion or removal of the at least one removable reagent container and the at least one slide during processing protocol steps," as required by claim 1.

*Rhett* also fails to disclose "wherein [a] first slide section and [a] second slide section are separated by [a] reagent section," as required by claim 9.

First, the Examiner states that "RHETT teaches the apparatus can also include a CCD camera (optical sensor) to image the stained slides . . ." (*Office Action*, p. 4, ll. 7-

9). Applicants respectfully disagree. *Rhett* discloses in column 14, lines 1-8,

[a]fter the staining run has completed, an "End Program Run" dialog box will be displayed and the computer will beep occasionally. At this point the user can print out a full copy of the program run log such that an Immunohistochemical Report can be created. The run information for any particular slide can be later recalled and used in conjunction with images of the stained slide captured with a CCD camera.

Accordingly, *Rhett* fails to disclose that the actual staining apparatus includes a CCD camera. *Rhett* merely suggests that information from a slide may be later recalled and used in conjunction with images of the stained slide captured with a CCD camera. Furthermore, *Rhett* fails to teach or suggest a control element which monitors insertion or removal of at least one removable reagent container and at least one slide during processing protocol steps.

Second, the Examiner states that, "RHETT . . . teaches the sample slides are in four racks . . . but does not teach the reagent section between the slide sections . . . [I]t has been held that rearranging parts of an invention involves only routine skill in the art (*In re Japikse*, 86, USPQ 70; MPEP 2144.04 (VI-C))." (*Office Action*, p. 4, ll. 11-18).

Applicants respectfully disagree.

As stated in MPEP § 2144.04, with respect to the *In re Japikse* case,

[c]laims to a hydraulic power press which read on the prior art except with regard to the position of the starting switch were held unpatentable because shifting the position of the starting switch would not have modified the operation of the device.

MPEP § 2144.04 further states,

[t]he mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims on appeal is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation or reason for the worker in the art, without the benefit of appellant's specification, to make the necessary changes in the reference device. *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984).

Accordingly, in view of *In re Japikse* and *Ex parte Chicago Rawhide Mfg. Co.*, the rejection of claim 9 under 35 U.S.C. § 102(b) is improper. First, the claimed arrangement of the first and second slide sections and the reagent section was specifically invented to improve the operation of the automatic staining apparatus. As stated on page 7, lines 7-13 of Applicants' specification,

the apparatus comprises at least two staining sections separated by a reagent section, that is they may be arranged so that at least some of the tissue samples are closer to at least some of the reagent containers. Hereby, the movements required by the robotic head in order to reach all the slides may be significantly limited and the capacity of the staining apparatus can hereby be increased, just as a reduction in the time for running the staining protocols or other advantages may be achieved.

Second, *Rhett* provides no motivation or reason for the worker in the art, without the benefit of Applicants' specification, to make the necessary changes in *Rhett's* automatic tissue staining device.

Accordingly, with respect to independent claim 1, *Rhett* fails to teach Applicants' claimed combination, including, *inter alia*:

at least one removable reagent container positioned within a reagent section;

at least one slide; . . .

a control element to which said robotic element is responsive; and

an image-capture 2-D optical sensor configured to two dimensionally image at least one element in said automatic staining apparatus,

wherein the control element monitors insertion or removal of the at least one removable reagent container and the at least one slide during processing protocol steps.

With respect to independent claim 9, *Rhett* fails to teach Applicants' claimed combination, including, *inter alia*:

wherein [a] first slide section and [a] second slide section are separated by [a] reagent section.

Since *Rhett* fails to disclose each and every element of independent claims 1 and 9, *Rhett* fails to anticipate claims 1 and 9. Therefore, Applicants respectfully request that this rejection be withdrawn.

New independent claims 35 and 36 are also patentably distinguishable over *Rhett*. For example, claim 35 recites in pertinent part an automatic staining apparatus comprising "at least one sample placed on a slide in a slide rack; . . . [and] a control element to which [a] robotic element is responsive . . . , wherein the control element monitors insertion or removal of the at least one slide rack during processing protocol steps"; and claim 36 recites a method of staining tissue samples in an automatic staining apparatus comprising the steps of "providing at least one slide; providing at least one removable reagent container; [and] . . . feeding . . . image data to a control element to which [a] robotic element is responsive, wherein the control element monitors insertion or removal of the at least one slide and the at least one removable reagent container during processing protocol steps." Accordingly, at least for the

reasons similar to those discussed above, *Rhett* fails to disclose each and every element of independent claims 35 and 36, and thus, fails to anticipate claims 35 and 36.

#### **IV. 35 U.S.C. § 103(a) REJECTION**

Claims 2-8 and 10-34 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Rhett* in view of *Ganz*. Applicants respectfully disagree with the Examiner's arguments and conclusions and submit that independent claims 6-8, 10, 17, 21, 25, and 30 distinguish over *Rhett* and *Ganz* at least for the reasons described below. However, in an effort to expedite prosecution, claims 6-8, 10, 17, 21, 25, and 30 have been amended and Applicants respectfully submit that *Rhett* and *Ganz* do not teach or suggest claims 6-8, 10, 17, 21, 25, and 30 as currently amended. Applicants further submit that the rejections of claims 20, 24, and 31 have been rendered moot by the cancellation of those claims, without prejudice or disclaimer.

The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. See M.P.E.P. § 2142, 8th Ed., Rev. 7 (July 2008). Such an analysis should be made explicit and cannot be premised upon mere conclusory statements. See *Id.* "[T]he framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). . . . The factual inquiries . . . [include determining the scope and content of the prior art and] . . . [a]scertaining the differences between the claimed invention and the prior art." M.P.E.P. § 2141(II). "Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art." M.P.E.P. § 2141(III).

As discussed above, *Rhett* appears to disclose a method and apparatus for automatic tissue staining. The automatic staining apparatus includes an electromechanical automatic staining device that is coupled to a personal computer system using an interface card. An autostainer control program runs on the personal computer system. The autostainer control program allows a user to simply program the automatic staining apparatus using simple commands entered in a graphical user interface. (*Rhett*, Abstract).

With respect to independent claim 6, the Examiner admits that "RHETT . . . does not explicitly disclose recording image data, robotic calibration points, and feeding the data to a control element." (*Office Action*, p. 7, ll. 1-3). Accordingly, the Examiner relies on *Ganz* and asserts, "GANZ teaches a camera that images the slides and software that analyzes the identification, positioning . . . and alignment information . . . provided by the camera and stores it . . ." (*Id.* at p. 7, ll. 3-6).

*Ganz* appears to disclose a high capacity microarray for spotting solution onto slides in an automated microarray dispensing device. The microarray dispensing device includes a camera 12 which acquires an image of a slide 4A1. The camera reads the bar code and inspects the positioning and alignment of the slide 4A1 on a locating plate 3A. The software then analyzes the position data and stores the information. The information stored is later used to adjust the positions of the slide 4A1 and a dispense head 6 to ensure accurate placement of solution on the slide 4A1. (*Ganz*, p. 5, line 29 - p. 6, line 4).

*Ganz*, however, fails to teach or suggest a method of identifying at least one property in an automatic staining apparatus comprising the steps of "recording



calibration reference points of the apparatus," as recited in independent claim 6. As discussed above, the automated microarray dispensing device in *Ganz* records reference points of the slide, not the apparatus.

With respect to independent claim 7, the Examiner admits that "RHETT . . . does not explicitly disclose the optical sensor responsive to the robotic element." (*Office Action*, p. 7, ll. 12-14). Accordingly, the Examiner relies on *Ganz* and asserts, "GANZ teaches the camera (optical sensor) images the slide after the linear actuator (robotic element) moves the slide under the dispense head . . ." (*Id.* at p. 7, ll. 14-16).

Such teaching, even if present in *Ganz*, however, fails to teach or suggest a method of staining samples in an automatic staining apparatus comprising the steps of "recording calibration reference positions for said slide racks," as recited in independent claim 7. As discussed above, the automated microarray dispensing device in *Ganz* records reference points of the slide, not the slide racks.

With respect to independent claim 8, the Examiner admits that "RHETT . . . does not explicitly disclose the optical sensor adapted to locate reference features for self calibration." (*Office Action*, p. 8, ll. 5-7). Accordingly, the Examiner relies on *Ganz* and asserts, "GANZ teaches an automated dispensing device to place reagents on slides in which a camera (optical sensor) images each slide and inspects (adapted to locate) the positioning and alignment of the slide . . ." (*Id.* at p. 8, ll. 7-10).

Such teaching, even if present in *Ganz*, however, fails to teach or suggest an automatic staining apparatus "wherein [a] control element monitors insertion or removal of [a] slide during processing protocol steps," as recited in independent claim 8.

With respect to independent claim 10, the Examiner admits that "RHETT teaches the claimed invention . . . except for one element comprising an optical identification element having reiterated information." (*Office Action*, p. 8, ll. 15-17). Accordingly, the Examiner relies on *Ganz* and asserts, "GANZ teaches the slides having identification information comprising unique 2D bar codes which are reiterated lines . . ." (*Id.* at p. 8, ll. 17-19).

Such teaching, even if present in *Ganz*, however, fails to teach or suggest an automatic staining apparatus "wherein [a] control element uses [an] optical identification element to monitor insertion or removal of [a] slide during processing protocol steps," as recited in independent claim 10.

With respect to independent claim 17, the Examiner admits that "RHETT teaches the claimed invention . . . except for a computer image biological analysis element." (*Office Action*, p. 9, ll. 7-8). Accordingly, the Examiner relies on *Ganz* and asserts, "GANZ teaches the control computer has software to inspect the stored camera images after reagent deposition onto a slide containing a biological sample . . ." (*Id.* at p. 9, ll. 9-11).

Such teaching, even if present in *Ganz*, however, fails to teach or suggest an automatic staining apparatus "wherein [a] 2-D optical sensor records a first image of . . . at least one sample before staining and records a second image of the sample after staining," as recited in independent claim 17.

With respect to independent claim 21, the Examiner admits that "RHETT . . . teaches the claimed invention except for biologically analyzing image data of a sample

with a computer." (*Office Action*, p. 9, ll. 12-14). Accordingly, the Examiner relies on *Ganz* and asserts, "GANZ teaches the control computer has software to inspect the stored camera images after reagent deposition onto a slide containing a biological sample . . ." (*Id.* at p. 9, ll. 14-16).

Such teaching, even if present in *Ganz*, however, fails to teach or suggest a method of identifying at least one property in an automatic staining apparatus comprising the steps of "feeding . . . image data to a control element to which [a] robotic element is responsive . . . , wherein the control element monitors insertion or removal of [a] slide rack during processing protocol steps," as recited in independent claim 21.

With respect to independent claim 25, the Examiner admits that "RHETT . . . teaches the claimed invention except for biologically analyzing image data of a sample with a computer." (*Office Action*, p. 9, ll. 17-19). Accordingly, the Examiner relies on *Ganz* and asserts, "GANZ teaches the control computer has software to inspect the stored camera images after reagent deposition onto a slide containing a biological sample . . ." (*Id.* at p. 9, ll. 19-21).

Such teaching, even if present in *Ganz*, however, fails to teach or suggest a method of staining tissue samples in an automatic staining apparatus comprising the steps of "feeding . . . image data to a control element to which [a] robotic element is responsive . . . , wherein the control element monitors insertion or removal of . . . at least one sample during processing protocol steps," as recited in independent claim 25.

With respect to independent claim 30, the Examiner admits that "RHETT . . . teaches the claimed invention except for a multifunction optical sensor." (*Office Action*,

p. 10, ll. 1-3). Accordingly, the Examiner relies on *Ganz* and asserts, “the camera (optical sensor) of GANZ is disclosed to read barcodes and inspect the positioning and alignment of a slide (multiple functions) . . .” (*Id.* at p. 10, ll. 3-5).

Such teaching, even if present in *Ganz*, however, fails to teach or suggest an automatic staining apparatus “wherein the multifunction optical sensor automatically identifies insertion of new slides and new reagent containers to the staining apparatus,” as recited in independent claim 30.

As explained above, the elements of independent claims 6-8, 10, 17, 21, 25, and 30 are neither taught nor suggested by the cited references and no reason has been clearly articulated as to why the claims would have been obvious to one of ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent claims 6-8, 10, 17, 21, 25, and 30, and claims 2-5, 11-16, 18, 19, 22, 23, 26-29, and 32-34, which correspondingly depend from claims 6-8, 10, 17, 21, 25, and 30. Claims 2-8, 10-19, 21-23, 25-30, and 32-34 are therefore patentable over *Rhett* and *Ganz*, and Applicants request that the rejection of claims 2-8 and 10-34 under 35 U.S.C. § 103(a) be withdrawn.

## **V. NEW CLAIMS**

New claims 35 and 36, though of different scope, recite limitations similar to the independent claims set forth above. For example, claim 35 recites in pertinent part an automatic staining apparatus comprising “at least one sample placed on a slide in a slide rack;. . . [and] a control element to which [a] robotic element is responsive . . . , wherein the control element monitors insertion or removal of the at least one slide rack during processing protocol steps”; and claim 36 recites a method of staining tissue

samples in an automatic staining apparatus comprising the steps of "providing at least one slide; providing at least one removable reagent container; [and] . . . feeding . . . image data to a control element to which [a] robotic element is responsive, wherein the control element monitors insertion or removal of the at least one slide and the at least one removable reagent container during processing protocol steps." Claims 35 and 36 are therefore allowable for at least the reasons presented above.

## **VI. CONCLUSION**

Applicants respectfully submit that claims 1-19, 21-23, 25-30, and 32-36 are in condition for allowance.

The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

In view of the foregoing, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

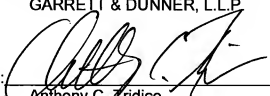
Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account 06-0916.

Respectfully submitted,

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